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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,670	07/28/2003	Suyue Qian		8567

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EXAMINER
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YU, MELANIE J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/628,670

Applicant(s)

QIAN, SUYUE

Examiner

Melanie Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-12 are rejected as failing to define the invention in the manner required by 35 U.S.C. 112, second paragraph.

The claim(s) are narrative in form and replete with indefinite and functional or operational language. The structure which goes to make up the device must be clearly and positively specified. The structure must be organized and correlated in such a manner as to present a complete operative device. The claim(s) must be in one sentence form only. Note the format of the claims in the patent(s) cited.

Claim 1 fails to provide a preamble reciting whether the claimed invention is a method or a product and fail to provide a body reciting positive method or product limitations. For the purposes of examination the claim will be examined as a product claim since the dependent claims indicate products.

Claims 1-12 fail to recite transitional claim language of: "comprising", "consisting of" or "consisting essential of".

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Claim 2 fails to recite any structural limitations fails to recite any specific product limitations for the detection system that allow for different detection principles.

Claim 4 recites the phrase "various materials" which is vague because it is unclear what or how many materials are required to fill the detection and reference cells in order to provide sufficient light transmission properties.

Claim 5 recites "the chemical reagent, affinity reagent antibody, antigen or proteins", in lines 1-2 of the claim. There is insufficient antecedent basis for these limitations in the claims.

Claim 6 recites "colloidal gold" in parenthesis and claim 7 recites "alkaline phosphatase and horse radish peroxidase etc." in parenthesis. It is unclear whether metallic sols are limited to colloidal gold and similarly, whether enzymes are limited to alkaline phosphatase and horse radish peroxidase or whether other metallic sols or enzymes are encompassed.

Regarding claims 7-9, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 8 recites the phrase "various chemical reactions", it is unclear what is meant by the term various. It is unclear whether the chemical reactions are limited to those listed in the claim and whether more than one chemical reaction is present in the test strip.

Claim 9 recites the phrase "various immunoassays", it is unclear what is meant by the term various. It is unclear whether the various immunoassays are limited to the types of immunoassays listed and whether more than one immunoassay is present in the test strip.

Claim 10 recites "any other position", it is unclear whether the test strip may be any position or whether certain positions are required for detection. Claim 10 recites "the

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detection system" in line 2 of the claim. It is unclear what is encompassed by "the detection system" because there is no antecedent basis for this phrase in the claims.

It is unclear whether the detection and reference cell of claim 11 are the same detection and reference cells of claim 3. Furthermore, it is unclear what is encompassed by "any shape and any size to accommodate the requirements of any particular test". It is unclear what test is performed on the detection and reference cells and what requirements are required for that test. It is unclear what shape is required or how one would determine the required shape of the detection and reference cells to accommodate the particular test. It is unclear whether the recited "particular test" is the detection technique of transmittance recited in claim 1. Claim 11 also recites "the requirements" in line 2 of the claim. There is lack of antecedent basis for this limitation in the claims. Furthermore, claim 11 recites "reference cells" and it is therefore unclear whether more than one reference cell is present.

Regarding claim 12, the phrase "or other means" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or other means"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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3. Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated Klopfer et al. (US 6,696,240).

Klopfer et al. teach a system comprising a chromatographic test strip detected with transmittance detection in a multi-step test (col. 5, lines 25-30; col. 6, lines 8-11) to quantitate analytes in biological fluids (abstract, last sentence; col. 14, lines 59-62), wherein fluorescence may also be used for detection (col. 6, lines 8-11).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claims 3-6 and 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klopfer et al. (US 6,696,240) in view of Van Deusen et al. (US 5,132,097).

Klopfer et al., as applied to claim 1, teach a system comprising a chromatographic test strip, wherein analyte are quantified with transmittance detection, comprising: a detection cell (col. 5, lines 60-66), flow passages (col. 5, lines 38-41), an absorbent portion (col. 5, lines 56-59) and a strip frame (100, Fig. 7, strip frame contains test strip), but fail to teach a reference cell.

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Van Deusen et al. teach a test strip comprising a detection cell and a reference cell (col. 5, lines 53-58), wherein analyte is quantified by transmittance detection (col. 5, lines 53-58; col. 2, lines 65-67), in order to provide accurate quantitative value of the amount or concentration of an unknown analyte (col. 3, lines 7-21).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Kloepfer et al., a reference cell in addition to a detection cell as taught by Van Deusen et al., in order to provide more accurate quantification of the amount or concentration of unknown analyte in a sample by comparison to a control or standard area.

Regarding claims 4-5, Van Deusen et al. teach the detection and reference cell filled with materials having light transmission properties (test and control/standard regions have transparent material, col. 5, lines 53-58) and the chemical reagent (specific binding reactor) is bound to the light transmission materials by simple adsorption (col. 3, lines 56-66).

With respect to claim 6, Van Deusen et al. teach labels being directly detectable (col. 4, lines 37-43), in order to provide an identifier for a sandwich assay. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the system of Kloepfer et al., a directly detectable label as taught by Van Deusen et al., in order to enhance a transmittance signal.

Regarding claims 8-9, Van Deusen et al. teach chemical reactions of enzymes, enzyme substrates, antibodies and antigens (col. 2, lines 55-67) and the test strip capable of performing sandwich assays (col. 4, lines 34-43).

With respect to claims 10-11, Van Deusen et al. teach the test strip being horizontal (test strip is shown in a horizontal position, Fig. 1-6) and the detection and reference cells being rectangular in shape (rectangular detection and standard regions, 42-49, Fig. 7).

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Regarding claim 12, Kloefer et al. teach a biological fluid passing through the strip by wicking (col. 5, lines 56-59).

5. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kloefer et al. (US 6,696,240) in view of Van Deusen et al. (US 5,132,097) further in view of Martens et al. (US 7,008,775).

Kloefer et al. in view of Van Deusen et al., as applied to claims 3 and 6 teach a test strip comprising a directly detectable label of a polystyrene bead, but fail to teach an indirect label of horse radish peroxidase.

Martens et al. teach that in test strip detection, indicator labels of either a bead made of polystyrene or an enzyme of horse-radish peroxidase may be used, in order to provide computer analysis.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute for the label of a polystyrene bead in the system of Kloefer et al. in view of Van Deusen et al., an enzyme label of horse-radish peroxidase as taught by Martens et al. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent labeling technique and since only the expected labeling effect would have been obtained. The use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on the economics and availability of components.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.




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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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Art Unit 1641



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